In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 08-335V
Filed: May 13, 2009

NOT TO BE PUBLISHED

JULIE DAVIS and RUFUS DAVIS parents and natural guardians of a minor child SETH DAVIS	*	
	*	Statute of Limitations; Markovich; Policy Arguments; Onset; Autism Untimely Filing
Petitioners,	*	
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Edward R. Downs, Jr., Ed Downs & Associates P.C., Riverdale, GA for petitioner

Linda S. Renzi, United States Department of Justice, Washington, DC, for respondent.

DECISION[1]

I. PROCEDURAL BACKGROUND

On May 6, 2008, petitioners Julie Davis and Rufus Davis filed a petition on behalf of

[1] Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public. Id.

their minor son, Seth Davis, pursuant to the National Vaccine Injury Compensation Program[2] ("the Act" or "the Program") alleging that Seth suffers from autism as a result of DPT and "other" vaccines received "[f]rom April 2, 2003 through March 24, 2008." Petition (hereinafter Pet.) at 1. Petitioners state that Seth received the DPT[3] vaccine in a series of five shots administered from April 2, 2003 through March 24, 2008. Id.; Petitioners' Exhibit (hereinafter P Ex) 3 at 1, filed May 15, 2008[4]. Petitioners allege that after the third or forth injection of DPT Seth's demeanor became "flat and unresponsive." Pet. at 1. Notably, petitioners categorize the time frame of this change as between November 2003 and February 2004. Id. Seth was subsequently determined to be severely autistic and his condition was also characterized as displaying mild to moderate retardation. P Ex 4 at 4. Respondent filed a Motion for Order to Show Cause on June 10, 2008 stating that, "petitioners have not established by a preponderance of the evidence that this claim was filed within the statutorily prescribed limitations period set forth in § 16(a)(2) of the National Childhood Vaccine Injury Act of 1986, *as amended*." Respondent's Motion for Order to Show Cause (hereinafter Motion to Show Cause) at 1, filed July 10, 2008 (citing 42 U.S.C. §§ 300aa-1 to -34 ("the Vaccine Act")). Petitioners were ordered to file a Response to respondent's Motion by no later than July 14, 2008. Order filed June 12, 2008. Petitioners filed petitioners' Response on July 16, 2008. Petitioners' Response to Respondent's Motion to Show Cause (hereinafter P Response), filed July 16, 2008. This case is now ripe for decision.[5] After considering the parties' arguments in conjunction with the record of this case it is clear to the undersigned that the Petition alleging the injury of autism was

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[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-10 et seq. (2006) ("Vaccine Act" or the "Act"). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

[3] While petitioners refer to the vaccination as DTP the medical records reflect the DTaP vaccination was given. P Ex 3 at 1, 11, 15, 16. This distinction is not material to the undersigned's analysis in the instant decision.

[4] Petitioners filed medical records initially on May 6, 2008, lettered as Exhibits A-E. Petitioners re-filed the Exhibits to reflect a numerical numbering system on May 15, 2008. P Ex 1-5, filed May 15, 2008. For clarity the undersigned will refer to the numbered exhibits in this decision.

[5] The delay in deciding this case was due to resolving several cases interpreting the Federal Circuit's decision in Markovich v. Sec'y of HHS, 477 F.3d 1353 (Fed. Cir. 2007), which have been decided and affirmed on appeal. See Cloer v. Sec'y of HHS, No. 05-1002, 2008 WL 2275574 (Fed. Cl. Spec. Mstr. May 15, 2008)(hereinafter Cloer I), aff'd, 85 Fed.Cl. 141 (Fed.Cl. Nov. 25, 2008)(Block, J.) (hereinafter Cloer II), appeal docketed, No. 2009-5052 (Fed. Cir. Mar. 9, 2009); Wilkerson ex rel. Wilkerson v. Sec'y of HHS, No. 05-232V, 2008 WL 4636329 (Fed. Cl. Spec. Mstr. Sept. 30, 2008)(hereinafter Wilkerson I), aff'd, slip op. (Fed. Cl. Apr. 3, 2009)(Hodges, J.)(hereinafter Wilkerson II); Bono v. Sec'y of HHS, No. 02-1085V, 2009 WL 270035 (Fed. Cl. Spec. Mstr. Jan. 16, 2009)(hereinafter Bono I), aff'd sub nom. Bono ex. rel. Bono v. Sec'y of HHS, 2009 WL 1220578 (Fed. Cl. Apr. 30, 2009)(Miller, J.)(hereinafter Bono II).

untimely filed.

II. Legal Standard

Pursuant to the Vaccine Act petitioners may be compensated for injuries caused by certain vaccines. 42 U.S.C. §§ 300aa-10 to -34. However, the Vaccine Act provides statutory deadlines for filing program petitions at § 300aa-16. In relevant part, the Vaccine Act provides:

> a vaccine set forth in the Vaccine Injury Table which is administered after [October 1, 1988], if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the **expiration of 36 months** after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury . . . .

§ 300aa-16(a)(2) (emphasis added). The Vaccine Act is a waiver of the United States' sovereign immunity and accordingly "must be strictly and narrowly construed." Markovich v. Secretary of HHS, 477 F.3d 1353, 1360 (Fed. Cir. 2007). The Federal Circuit has instructed "courts should be careful not to interpret a waiver in a manner that would extend the waiver in a manner beyond that which Congress intend." Id. (citing Brice v. Secretary of HHS, 240 F.3d 1367, 1370 (Fed. Cir. 2001)). The Circuit's decision in Markovich directly addressed the question of "what standard should be applied in determining the date of 'the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury,'" Markovich, 477 F.3d at 1356, by holding "'the first symptom or manifestation of onset,' for purposes of §300aa-16(a)(2), is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." Id. at 1360. Accordingly, petitioners have 36 months from the first recognizable sign of their alleged vaccine injury to file their claim.

The Circuit explained in Markovich that "the terms of the Vaccine Act demonstrate that Congress intended the limitation period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act." Id. at 1358. The Circuit elaborated that by choosing to "start the running of the statute of limitations period on the date the first symptom or manifestation of the onset occurs, Congress chose to start the running of the statute before many petitioners would be able to recognize with reasonable certainty, the nature of the injury." Id. The Court noted that the Act has "consistently been interpreted" to include "subtle" symptoms or manifestations of onset as triggers of the Act's statute of limitations. Id. The Court stressed that the words "symptom" and "manifestation of onset" are in the disjunctive as used in the Act and that the words have different meanings. Id. at 1357. Thus, **symptom** "may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury," whereas a **manifestation of onset** "is more self-evident of an injury and may include significant symptoms that clearly evidence an

injury." Id. Accordingly, the Court found that the Act's statutory standard of first symptom or manifestation of onset could include subtle symptoms that a petitioner would recognize "only with the benefit of hindsight, after a doctor makes a definitive diagnosis of the injury" and would be "recognizable to the medical profession at large but not necessarily to the parent." Id. at 1358, 1360 (citing Goetz v. Secretary of HHS, 45 Fed. Cl. 340, 342 (1999)). The undersigned's interpretation of Markovich was affirmed in Cloer II, Wilkerson II, and Bono II. Infra at n.5; Cloer II (explaining Markovich at 1358-1359 holds "the limitations period begins to run at the first occurrence of a symptom even though an exact diagnosis may be impossible until some future date when more symptoms or medical data are forthcoming."); Wilkerson II at 3 (parties agreed on date symptoms appeared, "the Chief Special Master had no choice, in light of *Markovich*, to rule that he lacked jurisdiction to consider the case on the merits."); Bono II at *5 (petitioners argue that the injury must be diagnosed as a vaccine-related injury to trigger the limitations period, "Markovich supports ...that a symptoms or manifestation need not be accepted as an injury specifically linked to vaccines; it only needs to be identifiable ...as a symptoms or manifestation of injury."). See also Lemire v. Sec'y of HHS, No. 01-617V, slip. op. at 9 (Fed. Cl. 2008) (Baskir, J.) ("Congress chose to start the running of the statute before many petitioners would be able to identify, with reasonable certainty, the nature of the injury."). Thus, the Circuit in interpreting the Act's statute of limitations, rejected applying a "subjective standard that focuses on the parent's view" of the timing of onset in favor of an "objective standard that focuses on the recognized standards of the medical profession at large." Markovich at 1360.

III. Analysis

Parties Arguments

The primary issue in this matter deals with the statute of limitations and the requirement that a petition be filed within "36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." §16(a)(2); Markovich at 1356.

Based on the medical records, respondent's position is that the Petition, filed on May 6, 2008, was not filed within the statutorily prescribed limitations period requiring filing of the Petition within thirty-six months of the first symptom or manifestation of onset of the alleged injury. Motion to Show Cause at 1, 3; see also §16(a)(2). Respondent argues that "according to the records filed to date, the first symptom or manifestation of onset of Seth's alleged vaccine-related injury occurred earlier than May 6, 2005." Motion to Show Cause at 2. Respondent cites to various places in Seth's medical records to support respondent's position that the first symptom or manifestation of onset occurred prior to May 6, 2005. Id. at 2-3 (citing P Ex 5 at 1,3; P Ex 3 at 11; P Ex 4 at 1). Thus, respondent states that the evidence fails to establish that the jurisdictional prerequisites of the Vaccine Act have been met. Id. at 5.

Petitioners do not argue with the current state of the law or the time frames set forth in respondent's Motion. P Response at para. 1. In fact, in the Petition petitioners state that Seth's

demeanor changed between November 2003 and February 2004, which is well beyond the Act's 36 month time period. Pet. at 1. However, petitioners present a policy argument that the statute of limitations period is "restrictive, inequitable, and does not square with the remedial purposes of the Vaccine Injury Act." P Response at para. 2. Petitioners further argue that the "manner in which the limitations period is now construed should be modified and expanded to comport with the legislative intent of the framers of the Vaccine Injury Act." Id. at para. 3. Lastly, petitioners appear to argue that the statute of limitations should not begin to run until petitioners' realization that their son's "symptoms were plainly vaccine-related." Id. at para. 5. Though not directly stated it appears to the undersigned that petitioners are making an argument based on the decision in Setnes. Setnes ex rel. Setnes v. Sec'y of HHS, 57 Fed. Cl. 175 at 179 (2003) (Futey, J.) (holding that cases such as autism where there is "no clear start to the injury..., prudence mandates that a court addressing the statute of limitations not hinge its decision on the 'occurrence of the first symptoms.'"). The Federal Circuit disagreed with the Setnes rationale in the Markovich decision. Infra at 3-4 (discussion of Markovich); see also Wilkerson I at 15-18 (detailed discussion of Setnes in light of Federal Circuit's decision in Markovich interpreting the limitations on actions provision in the Vaccine Act).

After the undersigned's review of the medical records there is no doubt that the Petition was not timely filed and must be dismissed. The undersigned will address (1) the issue of whether the Petition was timely filed, (2) petitioners' policy arguments and (3) petitioners' argument which appears to assert that the statute of limitations should not begin to run until the date of diagnosis.

It is clearly documented in the medical records that Seth displayed signs or symptoms of his alleged injury as early as 2004. Clinic Notes from a December 8, 2004 office visit with Margaret P. Adam M.D. state the "parents did notice some unusual behaviors and speech delay," Seth displays "repetitive behaviors" and most notably "delay particularly in the area of speech development as well as some unusual, autistic-like behaviors." P Ex 5 at 1,3. The clinician also notes a family history of an older brother with a diagnosis of high functioning autism or Asperger Syndrome and a family history of a maternal male cousin through an aunt who has been diagnosed with autism. Id. at 2. Because of the similarities in behavior between Seth and his older brother the family was referred to a genetics clinic to rule out the possibility of an underlying genetic condition. Id. at 1. On an office visit dated February 9, 2005 at Potts & Smith Pediatrics and Adolescent Medicine the clinician notes records that Seth "[h]as autistic like behaviors" and "doesn't talk." P Ex 3 at 11. At this visit Seth was referred to the Marcus Institute for evaluation of his autistic behaviors and speech therapy.[6] Id. Seth also received his forth DTaP vaccination on February 9, 2005. Id. On May 6, 2005 Seth saw Sheila Balog, Ph.D, P.C., a licensed psychologist, for a developmental assessment. P Ex 4 at 1. The Developmental and Medical History section of his assessment states that "[as] an infant, he did not smile and would not interact with others." Id. Dr. Balog records that Seth received several past evaluations

[6]The parents informed Dr. Balog that Seth could not be evaluated at the Marcus Institute until he was 2 years of age and planned to take him for evaluation at that time. P Ex 5 at 1.

in April 2005.[7] Id. Seth's score from an evaluation through Baby's Can't Wait placed him at 10 months of age, far below Seth's age of over two years at the time of evaluation. Id. Additionally, Dr. Balog notes that an occupational therapy evaluation showed deficiencies in "sensory modulation" and a speech and language evaluation indicated "a severe and profound speech and language disorder." Id. Based on Seth's symptoms Dr. Balog diagnosed Autistic disorder and probably mild to moderate mental retardation. Id. at 4. Seth received a rating of severely autistic on the Childhood Autism Rating Scale. Id. at 6. Petitioners argue that the Petition was timely filed within thirty-six months of the date of "[p]etitioners' realization that Seth's symptoms were plainly vaccine-related," relying on the May 6, 2005 assessment by Dr. Balog, diagnosing autism and mild to moderate mental retardation. P Response at para. 5; see also P Ex 4 at 4.

Based on this history in the undersigned's view it is clear that the onset of symptoms of Seth's alleged injury occurred more than thirty-six months prior to the filing of the Petition on May 6, 2008. See P Ex 5 at 1 (date of visit Dec. 8, 2004 "autistic-like behaviors and absent speech," parents stated Seth has "unusual behaviors such as walking backwards," "licking objects," "repetitive behaviors"); P Ex 3 at 11 (Feb 9, 2005 office visit "autistic like behaviors" "refer [ ] for evaluation of autistic behavior"). The evidence of symptoms prior to May 6, 2005 renders the claim untimely filed. §16(a)(2). The Federal Circuit's decision in Markovich makes clear that the Act's statute of limitations begins running from the first objectively recognizable sign of the alleged vaccine injury. This sign may be "subtle" and only recognizable "with the benefit of hindsight, after a doctor makes a definitive diagnosis of the injury," and might be "recognizable to the medical profession at large but not necessarily to the parent." Markovich at 1358. In this case the medical records, which petitioners do not take issue with, unquestionably document that Seth displayed symptoms of autism prior to May 6, 2005, and thus this Petition was untimely filed. See P Ex 5 at 1; P Ex 3 at 11; P Response at para. 1 (petitioners do not argue with the time periods laid out in respondent's Motion).

Petitioners do not dispute the current state of the law. P Response at para. 1. Petitioners attempt to circumvent dismissal of petitioners' claim by arguing that the application of the statute of limitations as a hard-and-fast rule is restrictive, inequitable and "does not square with the remedial purposes of the Vaccine Act," or comport with the legislative intent of the Vaccine Act framers. P Response at para. 2, 3. These arguments and others were rejected by Judge Block in the recent Cloer II decision. Cloer II at*13 (Judge Block affirmed the undersigned's interpretation of the Vaccine Act's limitations period, stating "The 36-month limitations period for the Vaccine Act is neither unlawful nor unconstitutional."). Judge Block noted that the limitations period in the Vaccine Act is a waiver of sovereign immunity and must be strictly construed. Cloer II at *6 (citing Brice v. Sec'y of HHS, 240 F.3d 1367 (Fed. Cir. 2001)(the limitations period "is a condition on the waiver of sovereign immunity by the United States, and

[7]The actual evaluation reports referenced were not filed into the record. The information regarding the evaluations was presented as part of the Developmental and Medical History portion of Dr. Balog's report.

courts should be careful not to interpret [a waiver] in a manner that would extend the waiver beyond that which Congress intended.")). In addition, Judge Block relied on Brice for the proposition that equitable tolling does not apply to tolling the statute of limitations under the Vaccine Act. Id. (citing Brice at 1372-74). Judge Block also thoroughly analyzed various equal protection and due process constitutional challenges to the 36 month limitations period under §16(a)(2). Id. at *6-11. He emphasized that it is clear that the statute of limitation is only subject to a rational basis review. Id. at *10. The Vaccine Act does not implicate a fundamental right. Id. at *10-11 (citing Black v. Sec'y of HHS, 93 F.3d 781, 787 (1996)). As Judge Block stated:

> [T]here can be no question that applying the Vaccine Act's limitation period is rationally related to the dual legitimate legislative purposes undergirding the Vaccine Act: (1) the settling of claims quickly and easily, and (2) the protecting of manufacturers from uncertain liability making "production of vaccines economically unattractive, potentially discouraging vaccine manufacturers from remaining in the market." *Brice*, 240 F.3d at 1368.

Cloer II, at *11 (n.10 omitted). Additionally he noted the Blackmon court's observation that "[t]he Due Process Clause does not entitle every litigant to a hearing on the merits in every case" and while it is regrettable that certain litigants fail to discover and file their claims before the statute of limitations expires that does not render the statute of limitations unreasonable. Id. at *11 (citing Blackmon v. American Home Prods., 328 F.Supp.2d 647, 655-56 (S. D. Tex. 2004)). Petitioners have raised no arguments that have not been addressed and rejected in prior decisions.

Petitioners' policy-based arguments are best directed at Congress, as the judicial body has no authority to amend the statute. Black v. Sec'y HHS, 93 F.3d 781, 789 (Fed. Cir. 1996) ("...the task of refining a statutory scheme such as the Vaccine Act so that it more precisely accords with the purposes for which the Act was designed is the responsibility of Congress, not the courts."). Regarding petitioners' policy arguments, as my colleague noted in a similar case "while petitioners may have a *policy* argument of some appeal, they have failed to offer any meritorious *legal* reason why I should do anything except enforce the statute. . . ." Weinstein v. Sec'y of HHS, No. 02-2059V, 2004 WL 3088663, at *3 (Fed. Cl. Spec. Mstr. Oct. 25, 2004). Policy arguments concerning the wisdom of a statutory provision "must be directed to Congress, not a judiciary officer." Id.; Beck v. Sec'y of HHS. 924F.2d 1029, 1034 (Fed. Cir. 1991) ("Regardless of their merits, these policy arguments may be implemented only by Congress. Our duty is limited to interpreting the statute as it was enacted, not as it arguably should have been enacted."). The undersigned must apply the law as enacted, and the law as applied to this case requires petitioners' case be dismissed.

Lastly, petitioners argue that the statute of limitations should not begin to run until "[p]etitioners' realization that Seth's symptoms were **plainly vaccine-related**." P Response at para. 5 (emphasis added)(petitioners' indirect reference to the May 6, 2005 office visit diagnosing autism and mild to moderate retardation, see P Ex 4). Although not directly stated, petitioners' reliance on the date of diagnosis for triggering the running of the statute of

limitations relies on the rationale in Setnes. In Markovich the Federal Circuit found a "significant problem with the rationale of Setnes" in that Setnes "effectively" required evidence of a "symptom *and* manifestation" whereas the Act requires either a symptoms or manifestation of onset, whichever occurs first, to trigger the statute of limitations. Markovich at 1358. The undersigned's analysis of Setnes post-Markovich is that although not directly stated, the Markovich decision appears to have found that Setnes was incorrectly decided. See Cloer I, 2008 WL 2275574 (Fed. Cl. Spec. Mstr. May 15, 2008), aff'd, 85 Fed.Cl. 141 (Fed.Cl. Nov. 25, 2008) (Block, J.) (explaining Markovich holds "the limitations period begins to run at the first occurrence of a symptom even though an exact diagnosis may be impossible until some future date when more symptoms or medical data are forthcoming."), appeal docketed, No. 2009-5052 (Fed. Cir. Mar. 9, 2009); Wilkerson I, No. 05-232V, 2008 WL 4636329 (Fed. Cl. Spec. Mstr. Sept. 30, 2008), aff'd slip op. (Fed. Cl. Apr. 3, 2009) (Hodges, J.); Bono I, No. 02-1085V, 2009 WL 270035 (Fed. Cl. Spec. Mstr. Jan. 16, 2009), aff'd 2009 WL 1220578 (Fed. Cl. Apr. 30, 2009) (Miller, J.); Hoogacker v. Sec'y of HHS, No. 07-800V, 2009 WL 321264 (Fed. Cl. Spec. Mstr. Jan. 23, 2009); Hoogacker v. Sec'y of HHS, No. 07-795V, 2009 WL 321269 (Fed. Cl. Spec. Mstr. Jan. 23, 2009). In Cloer I, petitioner raised similar arguments, essentially asking the undersigned to "apply the more lenient subjective statute of limitations period" found in Setnes. Cloer II at *3 (citing Setnes, 57 Fed.Cl. 175 (2003) (Futey, J.) (Holding that limitations period begins to run only when subtle symptoms of injury become clearly apparent and the onset of the manifestation of the disease can be diagnosed by a "treating physician")). In Cloer II Judge Block affirmed the undersigned's application of Markovich, stating that he "correctly observed that [t]he Federal Circuit was very clear that diagnosis is not the test for purposes of the statute of limitations.'" Cloer II at *9 (citing Cloer I at *8). Petitioners' arguments in reliance on the date of diagnosis do not survive the Markovich decision and the undersigned's repeated affirmance of his interpretation of Markovich. For the above-stated reasons the undersigned declines to apply Setnes in analyzing the timeliness of the filing of the Petition

In the case at hand, petitioners do not contest respondent's factual contentions or interpretation of the Federal Circuit's binding precedent. Application of the law to the facts of this case clearly finds petitioners' claim untimely filed. Petitioners' policy-based arguments cannot be applied to counter that result. Accordingly, the undersigned finds that petitioners' claim must be dismissed as petitioners have not proven by a preponderance of the evidence that the petition was filed within "36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury" as required by the Vaccine Act. Petitioners' claim is dismissed. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

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Gary J. Golkiewicz
Chief Special Master